K123971

MAY 2 2013

1.0 510(k) Summary

510(K) Owner:	CYNOSURE, INC. 5 Carlisle Road Westford, MA 01886
Contact:	Irina Kulinets VP of Regulatory Affairs and Quality Systems Cynosure, Inc. Telephone: 978-367-2350
Manufacturer:	CYNOSURE, INC. 5 Carlisle Road Westford, MA 01886 Telephone: 978-256-4200
Date Prepared:	December 21, 2012
Trade name:	Cynosure 1064nm Diode Laser
Common name:	Infrared Lamp
Classification name:	21 CFR 890.5500
Product Code(s):	ILY (lamp, infrared, therapeutic heating)
Classification:	Class II
Review Panel:	General & Plastic Surgery

Predicate Devices (Claiming Substantial Equivalence):

Biolase Technology, Inc.
ezlase™
K083595

CYNOSURE, INC.
HILT Family Laser
K051537

CYNOSURE, INC.
SmoothShapes XV® System
K100230

Summary Description of the Device:

The Cynosure 1064nm Diode Laser is the laser device that delivers laser energy in the 1064nm wavelength. The Cynosure 1064nm Diode Laser is a non-invasive device that emits light energy to for the purpose of causing the therapeutic elevation of tissue temperature.

The Cynosure Diode laser is a compact diode laser system. The Cynosure Diode laser's overall size, cooling needs, and electrical service requirements are substantially reduced compared to other lasers with similar power capabilities.

Intended Use / Indications for Use:

The Cynosure 1064nm Diode Laser Device is intended to provide heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

Technological Characteristics:

The Cynosure 1064nm Diode Laser has equivalent technological characteristics and fundamental scientific technology as the FDA cleared ezlase™ (Biolase Technology, Inc.), the Cynosure HILT Family Laser (El En) and the Cynosure SmoothShapes XV® System, K083595, K051537 and K100230, respectively.

Performance Standards:

This device conforms to the Laser Performance Standard (21 CFR 1040). No additional performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Performance Data:

Performance (bench) testing summaries are included in this submission.
In testing at 63W and 73W device increased and maintained the tissue temperature at 40 – 45°C

Substantial Equivalence:

There are no differences in technological characteristics or performance specifications between the ezlase™ (Biolase Technology, Inc.) and the Cynosure HILT Family Laser (El En) K083595, K051537 respectively and Cynosure's proposed device that would affect safety and efficacy. Both predicates utilize the same fundamental technology and the same indications for use as the proposed device. The Cynosure 1064nm Diode Laser has the equivalent delivered maximum fluence cleared previously by the FDA under 510(k) K100230 (SmoothShapes XV® System). The Cynosure 1064nm Diode Laser is as safe and effective as the predicate devices which have equivalent intended use/indications for use, principle of operation, technological characteristics and similar performance specifications. The Cynosure 1064 Diode Laser is substantially equivalent to the predicate devices and does not raise any additional questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 2, 2013

Cynosure, Inc.
% Ms. Irina Kulinets
VP of Regulatory Affairs and
Quality Systems
5 Carlisle Road
Westford, Massachusetts 01886

Re: K123971
Trade/Device Name: Cynosure 1064nm Diode Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: April 16, 2013
Received: April 17, 2013

Dear Ms. Kulinets:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123971

Device Name: Cynosure 1064nm Diode Laser

Indications For Use: The Cynosure 1064nm Diode Laser Device is intended to provide heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.05.02 12:18:41 -04'00'

(Division Sign-Off) For MXM

Division of Surgical Devices

510(k) Number __K123971_____